

510K Summary

APR - 2 2008

K072551

LD-I 75 and LD-I 200tm

10 August 2007

Sponsor

Consultant

Meditech International Inc. 411 Horner Ave., Unit #1 Etobicoke, Ontario, Canada M8W 4W3 Voice 416 251 1055 Fax 416 251-2446 Email: mslonchka@meditech-bioflex.com	Mr. Richard Keen Compliance Consultants 1151 Hope Street Stamford, CT 06907-1659 Voice 203 329 2700 Fax 203 329 2345 Email: rkeen@fda-complianceconsultants.com
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Proprietary Name:	LD-I 75 and LD-I 200tm
Common Name:	LD-I 75 and LD-I 200tm
Device Classification Name:	lamp, non-heating, for adjunctive use in pain therapy
Classification Number:	21 CFR part 890.5500
Product Code:	NHN
Device Classification:	Class II
Establishment registration No. :	Not applicable (foreign manufacture)
Predicate Device:	K010175, K043353, K050342

Trademark Notice: All Trademarks used other than those of **Meditech International** are registered to their respective owners.

Confidentiality notice: All data contained in this application and all appendixes provided with this appendix or aided trade secrets or proprietary data which the sponsor requests are treated in accordance with law.

Device Description

The **BioFlextm System and related Treatment Heads** are described as a Class II Low Level Laser treatment heads that apply energy, which penetrates the skin surface to the underlying tissues, and triggers normal cellular functions that lead to a surgery-free, drug-free, and low cost benefit to the patient, the practitioner and the health care system.

Intended Use

The **intended use** of this device is for trained health care professionals to incorporate this technology into his/her scope of practice for the benefit of the patient and to treat those patients with specific pathologies using specific protocols.

Technological Characteristics and Substantial Equivalence

The **scientific concept** on which this device is based is the principle that by stimulating a local area with low level laser, pain is relieved.

Performance Testing

A series of factory calibration tests are conducted to verify the device is accurate and calibrated (and can maintain calibration over its useful life). The **BioFlextm System and related Treatment Heads** has benefited from design, development, testing and production procedures that conform to Quality Systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Meditech International, Inc.
% Compliance Consultants
Mr. Richard Keen
1151 Hope Street
Stamford, Connecticut 06907

APR - 2 2008

Re: K072551
Trade/Device Name: LD-I-75 and LD-I-200™
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: NHN
Dated: March 3, 2008
Received: March 5, 2008

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (If known): K072551

Device Name: *LD-I-75 and LD-I-200[™]*

The *LD-I-75 and LD-I-200[™]* treatment heads are indicated for adjunctive use in the temporary relief of pain associated with rotator cuff tendonitis.

Neil R. Ogle for review
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K 072551

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over - The - Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)